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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,040	03/01/2002	Joseph C. Cauthen	08442.0002-04	8078

22852 7590 03/07/2007  
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER  
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WASHINGTON, DC 20001-4413

EXAMINER
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ISABELLA, DAVID J

ART UNIT	PAPER NUMBER
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3738

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/07/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

ED

**Office Action Summary**

Application No.

10/085,040

Applicant(s)

CAUTHEN, JOSEPH C.

Examiner

DAVID J. ISABELLA

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 9/26/2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 102-107, 109-133, 137-139, 141, 142, 145-149, 151-175 and 179-181 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 102-107, 109-133, 137-139, 141, 142, 145-149, 151-175 and 179-181 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                          | 6) <input type="checkbox"/> Other: _____                          |

***Status of the Claims***

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Applicant's amendment filed on 9/26/2006 has been entered. Currently, claims 102-112, 114-133, 137-139, 141, 142, 145-149, 151-175, 179-181 are pending for consideration.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

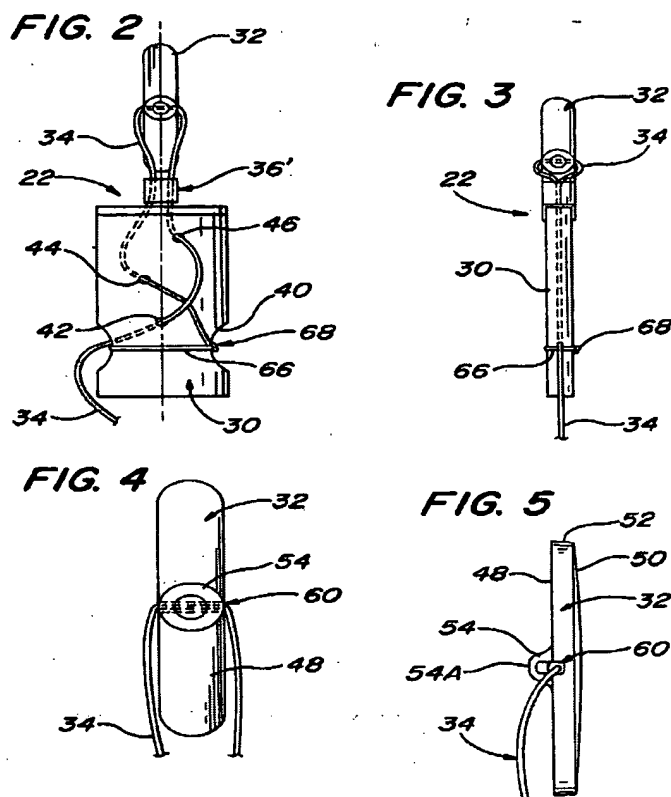
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 102-108, 114-118, 120-127, 130, 131, 133, 137-139, 141, 142, 145-149, 156-160, 162-169, 172, 173, 175, 179-181 are rejected under 35 U.S.C. 102(b) as being anticipated by Nash [5411520 or 5312435].

Nash discloses a closure device including a main body portion(30) having proximal and distal ends; and an extension (32) having an axis projecting along a

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reference plane that is lateral from the main body. The extension is flexible and can



deflect from its reference plane.

Claim 103, see sutures 34 of Nash.

Claim 104, see column 6, lines 1+ of Nash

Claim 105, see figure 6 of Nash.

Claim 106, see figure 27.

Claim 107, see figure 5.

Claim 108, see column 3, lines 5+.

Claims 114-118, 120-127, 130, 131, 133, see columns 5 and 6 of Nash.

Claims 137-139, see figure 5 of Nash.

Claims 141, see figures 2-5.

Claim 142 see slot 40 of Nash.

Claims 145-147, see rejections to corresponding claims supra.

Claim 148, see rejection to claim 106 supra.

Claim 149, see rejection to claim 107 supra.

Claims 156-160, 162-169, 172, 173, 175, 179-181, see rejections to corresponding claims supra.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 109-111, 119-124, 128, 129, 151-153, 161-166, 170, 171 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nash and further in view of Gilson [5904703], Bao et al. (USPN 6,224,630) or Carr, Jr. et al (5733337). Nash discloses, generally, that the device is fabricated from collagen foam that is resorbable. Gilson teaches that the occluder device (60) is made from a compressible, porous polymeric foam in column 4, lines 30-31 and 55-58. Bao et al. teaches the occluder device also being made from a compressible, porous polymeric foam in column 3, lines 15-19 and

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column 5, lines 36-42. The foam can be made from bioresorbable collagen fibers and interwoven biocompatible polymeric fibrils that by nature provide a membrane, fabric or sheet or ePTFE (Claims 57,58,64-66,70-76; column 5, lines 56-57). These materials can be made sufficiently porous to permit tissue ingrowth into the material from surrounding tissue of the implant site. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Gilson and/or Bao et al. to make the polymeric material of the device (40) of Nash from the materials required by claims sufficient porosity to permit tissue ingrowth into the material from surrounding tissue of the implant site. When the device Nash, as modified by Gilson and/or Bao et al., is used to treat an intervertebral disc wall, the material of the device will facilitate regeneration of disc tissue by promoting tissue ingrowth from the surrounding annulus. See column 14, lines 14+ of Bao et al for teachings of equivalent fastening elements.

Carr, Jr. et al. teach a tissue repair fabric that can be implanted to repair, augment or replace structures including intervertebral discs (column 4, lines 43-53). The tissue repair fabric comprises collagenous tissue obtained from autograft, allograft or xenograft fascia lata or pericardium, in order for the fabric to undergo controlled biodegradation accompanied by adequate living cell replacement, or neo-tissue formation, such that the original implanted prosthesis is remodeled by the host's cells before it is degraded by host enzymes when implanted into the host. See column 2, lines 13-24, 36-38 and 65-66. Carr et al. also teaches the additional limitation of the

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tissue repair fabric including growth factors (claims 62 and 63; column 8, lines 13-15) in order to promote vascularization.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 102,112,1323,141,154,174 are rejected under 35 U.S.C. 102(b) as being anticipated by Montgomery et al (3707150).

Montgomery et al discloses an unitary, non-porous closure device including a main body portion having proximal and distal ends; and an extension having an axis projecting along a reference plane that is lateral from the main body. The extension is flexible and can deflect from its reference plane.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 102,112,131,132,141,154,173,174 are rejected under 35 U.S.C. 102(e) as being anticipated by Woods, et al (6493898).

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Woods, et al discloses an unitary, non-porous/porous closure device including a main body portion having proximal and distal ends; and an extension having an axis projecting along a reference plane that is lateral from the main body. The extension is flexible and can deflect from its reference plane.

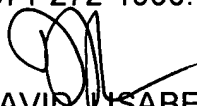
Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J. ISABELLA whose telephone number is 571-272-4749. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



DAVID J. ISABELLA  
Primary Examiner  
Art Unit 3738

DJI  
2/17/2007